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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,071	07/23/2001	Mayumi Tomikawa	522.1921D2	2943
21171	7590	04/07/2006	EXAMINER	
STAAS & HALSEY LLP SUITE 700 1201 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			BORIN, MICHAEL L	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/910,071	TOMIKAWA ET AL.
	<b>Examiner</b> Michael Borin	<b>Art Unit</b> 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 1/12/2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 13-15 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 13-15 and 24-26 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/12/2006 has been entered.

### ***Status of Claims***

1. Claims 13-15, 24-26 are pending. Claims 13,24 are amended.

Rejections not reiterated from previous Office actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 112, second paragraph.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13-15, 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. The rejection is applied for the following reasons.

A. Claims 13,24 are amended to add two additional steps, "determining" and "outputting". It is not clear what is the relation between the original method steps of "generating" and "calculating", and the new steps of "determining" and "outputting". It seems that the previously claimed steps are now irrelevant as the final result of the method, "outputting" is based only on the now added step of "determining". Please clarify.

B. Claims 13,24 are amended to add the final step of concluding that the functions of two structures are substantially equivalent. The meaning of the term "function" is not clear, the specification does not define the term and it is not clear what kind of function(s) is being defined based on similarity of 3-D coordinates. For example, if 3-D coordinates of an atomic group of a silicon semiconductor correlates with 3-D coordinates of an atomic group of a nucleic acid, what kind of function is determined to be "substantially equivalent". Further, it is not clear what constitutes a "function" for a "sequence of atoms" or for "a sequence of atomic groups".

C. The newly added step of "determining" addresses determining "degree of spatial similarity". The term "spatial similarity" is not specifically identified in the specification; the specification, although providing particular examples (Fig. 45), does not provide a standard for ascertaining the requisite criteria for determining "spatial similarity", and one of ordinary skills in the art would not be reasonably apprised of the scope of the invention.

D. Claims 13,24: The term "substantially equivalent" is a relative term which renders the claim indefinite.

**Claim Rejections - 35 USC § 101 (utility)**

3. Claims 13-15, 24-26 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The instant claims are drawn to a computer process of analyzing 3-D coordinates of "sequences of atoms or atomic groups of molecules" of two substances which results in outputting determination whether, based on similarity in 3-D structures, a function of the first substance is substantially equivalent to a function of the second substance. The claims do not recite any particular function or any other practical application of the method.

Specification describes examples in which a set of elements constituting a molecule is divided into subsets based on the secondary structures, and the subsets are related to each other based on the similarities of spatial position relationships of elements that belong to the subsets; further, specification describes evaluation of similarities of spatial position relationships of a plurality of subsets that are related to one another. See paragraphs [0298]-[0333]. Further, specification states that it is known that the three-dimensional structure of the substance is closely related to the function thereof;

however, no particular function linked to the three-dimensional structure is specified. See paragraphs [0011], [0021].

According to MPEP 2107.01 and as set forth in *Brenner v. Manson* (148 USPQ 689 (1966) and *In re Ziegler* (26 USPQ 2d 1600), a “useful invention” is one wherein the “usefulness” is “immediately apparent to those familiar with the technological field of the invention. As further set forth in MPEP 2107.01, a “use” to do further research, is not considered a “substantial utility” under 35 USC 101. As the structures being “assayed” are unknown/not identified in the claim, their utility is unknown. Neither a “function” correlated with the three-dimensional structure is identified. Thus, it is Examiner’s position that the claimed invention does not have a specific utility as it is not directed to any particular “function” of any compound or class of compounds. Further, the claimed invention does not have a substantial utility as more information and/or further research would be required for one skilled in the art to identify what particular functions are related to a 3-D structure and how a similarity in 3-D structures for unrelated compounds or fragments thereof is translated into a similarity in yet unidentified function.

For example, as discussed above, if 3-D coordinates of an atomic group of a silicon semiconductor correlates with 3-D coordinates of an atomic group of a nucleic acid, it is not clear determination regarding which function is being determined to be “substantially equivalent”, and it will take further research to identify how a similarity in 3-D structures for these unrelated compounds or fragments thereof is translated into a similarity in yet unidentified function. . Even where the claims encompass proteins, in the absence of any knowledge of identity, function, etc., of the proteins being compared,

nor any determination of a degree of similarity between two proteins, the claims do not provide an "immediately useful" result.

Further, the sets of three-dimensional coordinates are not limited to originate from two different structures, and the method may represent comparison of different groups of atoms of the same molecule. The specification does not disclose a utility for comparing different parts of the same compound or molecule and none is apparent

4. Claims 13-15, 24-26 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

#### **Claim Rejections - 35 USC § 101 (non-statutory)**

5. Claims 13-15, 24-26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The rejection is applied for the reasons of record and further in view of the following.

The instant claims are drawn to a computer process of analyzing 3-D coordinates of "sequences of atoms or atomic groups of molecules" of two substances which results in outputting determination whether, based on similarity in 3-D structures, a function of the first substance is substantially equivalent to a function of the first

substance is substantially equivalent to a function of the second substance. The claims do not recite any particular function or any other practical application of the method.

To be statutory, an invention must be directed to one of statutory categories enumerated in 35 USC § 101, or must produce a result which is useful, and tangible, and concrete. In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be "concrete," the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete result in the claim itself. In addition, a claim must be limited only to statutory embodiments. Thus, if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

For a claim to be "useful," the claimed method does not produce a result that is specific or substantial (see "utility" rejection above). For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world result. Further, the instant claims do not include any tangible result, i.e., the claims do not recite a practical application producing a real-world result. As the claims do not specify determination regarding which "function" is being made there is no evidence that such determination regarding an unidentified function produces a real-world result. Furthermore, the claims are not "concrete," i.e., they are not directed to a result that can

be substantially repeatable, because the claims are directed to analyzing point sets representing 3-D coordinates and the latter varies depending on the conditions of acquiring the coordinates; thus comparing sets obtained under different conditions would yield different, non-repeatable results.

***Claim Rejections - 35 USC § 102 and 103.***

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 13-15, 24-26 are rejected under 35 U.S.C. 102(b) as anticipated by Flaherty et al. (Proc. Natl. Acad. Sci. USA, 88, 5041-5045, 1991) or Mosimann et al.

Flaherty et al. describes comparison of muscle actin and heat shock cognate protein and demonstrate that calculating of rmsd between comparable spatial fragments shows close similarity of the structure of these proteins. See abstract. The reference concludes that the spatial similarity between actin and heat shock cognate protein suggest that there may be similarities in their functions. P. 5044-5045.

Mosimann et al. describe comparison of molecular models of P-30 protein and pancreatic RNase. The all atom superposition of active site residues of the P-30 and an identically minimized RNase structure has a root square deviation of 0.52A. Spatial

similarity in the structures suggest similar pyrimidine specificity, i.e., similar function.

See abstract.

Response to arguments

With respect to both art rejections, Applicant argues that the reference does not teach the invention as claimed by providing a full text of claim 13. Applicant's position regarding what specifically is not taught in the reference is not clear.

Examiner maintains that as the instant claims are drawn to method of analyzing three-dimensional structures by generating correspondence between set points describing two three-dimensional structures and calculating root mean square distance (rmsd) between the corresponding elements, the claims read on any reference teaching comparison of two three dimensional structures and calculating rmsd therefor. The references used in the rejection are exemplary of this commonly used approach to comparing 3-D structures.

***Double Patenting***

7. Claims 13-15, 24-26 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16,17 of co-pending application 09/909809 or claims 5-11,24 of co-pending application 09/910054. The referenced claims of both applications are drawn to methods of analyzing three-dimensional structures including steps of dividing points, generating correspondences and calculating rmsd, as instantly claimed.

Applicant responds that the rejection is "premature". Note, that as was stated in the rejection, the rejection is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Primary Examiner  
Art Unit 1631

mlb  
09/14/2005